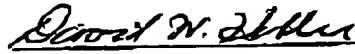

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being filed with Dianne Maggard of the United States Patent and Trademark Office by facsimile transmission on October 21, 2005 to facsimile telephone number (571) 273-0300.

41,071



David W. Hibler

(Reg. No.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Turner Jr. <i>et al.</i>	Group Art Unit:	1647
Application No.:	09/689,911	Appeal No.:	2005-2379
Filed:	10/11/2000	Examiner:	B. Bunner
Title:	Polynucleotides Encoding Human Galanin Family Proteins (As Previously Amended)	Atty. Docket No.:	LEX-0068-USA

RESPONSE TO ORDER UNDER 37 C.F.R. § 41.50(d) DATED SEPTEMBER 23, 2005**Mail Stop Appeal Brief - Patents**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Appellants acknowledge the receipt of the Order Under 37 C.F.R. § 41.50(d) ("the Order") mailed on September 23, 2005, which has been carefully reviewed and studied. Appellants address the issues raised in the Order below.

A one month non-extendable time limit for response is set forth in the Order. The response is thus due on October 23, 2005, which falls on a Sunday and is therefore extended to Monday, October 24, 2005, under 37 C.F.R. § 1.7. The response is therefore timely filed, and Appellants believe no fees are due in connection with this response. However, the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

RESPONSE

In the Appeal Brief filed on February 11, 2004 ("the Appeal Brief"), Appellants provide evidence of record that clearly establishes that the present application and claims meet the administrative requisites outlined in Example 10 of the Revised Interim Utility Guidelines Training Materials. Specifically, Appellants detail that the presently claimed sequence shares 100% identity at the amino acid level with the first 98 amino acids of a sequence that is described in a journal article by Ohtaki *et al.* (*J. Biol. Chem.* 274:37041-37045, 1999; "Ohtaki") as "Human Galanin-like Peptide (GALP)", and that these scientists have functionally characterized GALP, detailing that the processed porcine GALP (1-60) preferentially binds and activates the galanin receptor GALR2 relative to GALR1 (see Ohtaki at page 37045), and further, that the amino acid sequences surrounding the N- and C-terminal processing sites lie within the first 85 amino acids of GALP and are conserved between the human and porcine GALP (see Figure 3 of Ohtaki at page 37044).

In the Order at page 3, footnote 3 ("footnote 3"), the Board of Patent Appeals and Interferences ("the Board") states:

Appellants cite a paper published in December 1999 as describing and characterizing a protein that 'shares 100% identity at the amino acid level with the first 98 amino acids' with SEQ ID NO:2. The instant application, however, has an effective filing date of October 1999 and Appellants have not shown that the later-published paper reflects the state of the art as of the filing date.

With regard to the Board's contention that "Appellants have not shown that the later-published paper reflects the state of the art as of the filing date", Appellants respectfully point out that in the first Official Action on the merits in the present case, mailed on April 1, 2002 ("the First Action"), the Examiner made two references of record in the present case (the First Action at page 13): 1) Ohtaki; and 2) Ohtaki *et al.*, PCT Patent Application Publication Number WO 99/48920 ("WO 99/48920"). Appellants respectfully point out that WO 99/48920 was published in Japanese, so merely for the convenience of the Board Appellants focused their arguments on Ohtaki, which was published in English, instead of WO 99/48920. However, Appellants note for the record that WO 99/48920 discloses the DNA and amino acid sequence of porcine GALP (SEQ ID NOS:27 and 29, respectively), as well as the amino acid sequences of the processed porcine, rat, and human GALP (1-60) (SEQ ID NOS:31, 33, and 34, respectively), and also discloses that GALP preferentially activates the galanin receptor GALR2 relative to GALR1 (see Figure 2 of WO 99/48920), exactly as was disclosed in Ohtaki. Importantly, WO 99/48920 was published on

September 30, 1999, 12 days before the effective filing date of the present application (October 12, 1999). Appellants further note that Ohtaki was received for publication on October 8, 1999 (see Ohtaki at page 37041), 4 days before the effective filing date of the present application. Therefore, as the art made of record by the Examiner in the First Action was clearly pre-filing date art, Appellants were not aware that "the state of the art as of the filing date" was an issue in the present case, since the art of record establishes on its face that the information contained therein "reflects the state of the art as of the filing date". Appellants respectfully note that in a recent Decision on Appeal in a commonly assigned application (see Appeal No. 2005-1285, decided August 31, 2005), the Board has looked favorably on pre-filing date evidence in support of patentability in overcoming rejections under 35 U.S.C. § 101 as allegedly lacking a patentable utility, and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility.

With respect to the Order itself, the Board states that "(t)he Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-1732" (the Order at page 3, emphasis in original), and thus, the Board "require Appellants to explain why we should again address the same line of argument in this case" (the Order at page 4). Specifically, the Board states:

since the same arguments were considered and thoroughly addressed in Appeal No. 2004-1732, why would the previous panel's treatment of those arguments not be dispositive here? In particular, why should the facts and arguments set forth in the briefing of this appeal lead to a different conclusion than that reached by the panel in Appeal No. 2004-1732, which rejected the same arguments? (the Order at page 4)

Appellants are somewhat confused by these statements, and thus the necessity of the Order, since the Board admits in footnote 3 that the Appeal Brief makes additional arguments that were not "made and rejected by the previous merits panel in Appeal No. 2004-1732". Specifically:

(i) in addition to the arguments quoted above [from Appeal No. 2004-1732], Appellants cite a paper published in December 1999 as describing and characterizing a protein that 'shares 100% identity at the amino acid level with the first 98 amino acids' with SEQ ID NO:2. The instant application, however, has an effective filing date of October 1999 and Appellants have not shown that the later-published paper reflects the state of the art as of the filing date. In addition, Appellants argue that they have made knock-out mice that show the protein encoded by the claimed polynucleotides is involved in inflammation. Appellants, however, have pointed to no evidence in the record to support these arguments - attorney argument is not evidence. Appellants' argument based on knock-out mice is unsupported by evidence in the

record and therefore unpersuasive. (Emphasis added)

Clearly, the arguments detailed in footnote 3, which were set forth by Appellants in the Appeal Brief, were neither “made and rejected by the previous merits panel in Appeal No. 2004-1732”, nor “considered and thoroughly addressed in Appeal No. 2004-1732”. Although the Board has briefly addressed these new arguments in footnote 3, Appellants respectfully question whether a footnote in an Order Under 37 C.F.R. § 41.50(d) is the proper forum for the disposition of new arguments not previously considered by the Board. As set forth by the U.S. Court of Appeals for the Federal Circuit (“the Federal Circuit”) in *Gechter v. Davidson* (43 USPQ2d 1030, (Fed. Cir., 1997)), “the Board is required to set forth in its opinions specific findings of fact and conclusions of law adequate to form a basis for our review” (emphasis added). To the best of Appellants’ knowledge, only a final Decision on Appeal from the Board is appealable to the Federal Circuit, not an Order Under 37 C.F.R. § 41.50(d), presently leaving Appellants no forum to argue the Board’s disposition of the new arguments set forth in the Appeal Brief, as detailed in footnote 3. Therefore, Appellants respectfully request that these arguments be “considered and thoroughly addressed” in the context of the present Appeal.

In summary, Appellants submit that facts and evidence supporting at least two assertions of utility are set forth in the Appeal Brief that were not addressed by the previous merits panel in Appeal No. 2004-1732. Appellants acknowledge that Appeal No. 2004-1732 dealt with some of the issues of utility set forth in the Appeal Brief. However, the prior rejection of *some* of Appellants’ assertions of utility should not end the present inquiry, for, as set forth in the Appeal Brief, the Federal Circuit has stated that only one credible assertion of utility is needed to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)). Additionally, Appellants note that all issues relating to patentable utility are required to be raised and contested in order to preserve such issues for appeal to the Federal Circuit, which has not yet determined the broader legality of the Patent Office’s imposition of a distinct and more onerous standard of utility for biotechnology sequence inventions. Furthermore, Appellants respectfully request that the Board consider that the evidence and facts of record in the present Appeal merit, if not logically require, an outcome opposite from that reached by the Board in Appeal No. 2004-1732. Therefore, Appellants respectfully request the Board to address all of the assertions of utility set forth by Appellants in the Appeal Brief, and to overrule the rejections

of claims 1-8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

October 21, 2005
Date

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Date: October 21, 2005

Phone:

Pages: 6 (including coversheet)

Re: Appeal No. 2005-2379
Application Serial Number: 09/689,911
Atty. Dkt. No. LEX-0068-USA

CC: File

•Comments:

Please find attached a Response to the Order Under 37 C.F.R. § 41.50(d) in reference to the above-referenced appeal. Please contact me at the number shown above if there are any questions.